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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,355	07/06/2001	H. Craig Dees	PHO-122	5998

7590 07/27/2005
COOK, ALEX, McFARRON, MANZO,
CUMMINGS & MEHLER, LTD.
Suite 2850
200 West Adams St.
Chicago, IL 60606

EXAMINER

EPPS FORD, JANET L

ART UNIT PAPER NUMBER

1633

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,355

Applicant(s)

DEES ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9-11,19,20 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-11,19,20 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5-23-05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 1-2, 9-11, 19-20 and 27 are currently pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. Line 1 of the specification as filed states that the instant application is based on provisional application USSN 60/218,464 filed July 14, 2000 which is a continuation in part of USSN 09/130,041, filed on August 6, 1998. This statement by applicants is improper, first applicants state that the instant application is "based on" USSN 60/218,464, Applicants should properly state that the instant application claims benefit under 35 USC 119(e) of US Application No. 60/218,464 filed July 14, 2000. Moreover, Applicants improperly state that the provisional application is a CIP of 09/130,041. This statement is also improper as per MPEP 201.07 [R-2] which states that "[A]n application claiming the benefits of a provisional application under 35 U.S.C. 119(e) **should not be called a "continuation"** of the provisional application since an application that claims benefit of a provisional application is a nonprovisional application of a provisional application, not a continuation, division, or continuation-in-part of the provisional application."

Response to Arguments

4. Applicant's arguments with respect to rejection of claims 1-4, 9-11, 19-22 and 27 set forth in the prior Office Action have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1, 9-11, 19 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Dees et al. (US Patent No. 6,331,286, filing date 12-21-1998).

7. The effective filing date of the instantly claimed invention is considered to be that of the provisional application USSN 60/218,464 filed July 14, 2000. Applicants are not granted the filing date of 09/130,041, filed on August 6, 1998, because application 09/130,041 does not recite the halogenated xanthene compounds specifically claimed in currently amended claim 1 and 19.

8. Claim 1 recites and injectable chemotherapeutic pharmaceutical composition, and claim 19 recites a chemotherapeutic pharmaceutical composition consisting of a disodium or dipotassium salt of a halogenated xanthene in aqueous solution, wherein said halogenated xanthene

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is a compound selected from the group consisting of 4,5,6,7-Tetrabromoerythrosin, Monobromoerythrosin, Dibromoerythrosin, Tribromoerythrosin, Monochloroerythrosin, Dichloroerythrosin, Trichloroerythrosin, Monofluoroerythrosin, Difluoroerythrosin, Trifluoroerythrosin, 2',7'-Dichloro-4,5,6,7-Tetrafluorofluorescein, 2',4,5,6,7,7'-Hexafluoro-fluorescein and 4,5,6,7-Tetrafluorofluorescein and wherein said pharmaceutical composition is for chemotherapeutic treatment of diseases of human and animal tissue.

The prior art is applied to the extent that it discloses compositions consisting of disodium or dipotassium salts of halogenated xanthene compounds in aqueous solution. The limitations “injectable chemotherapeutic” and “for chemotherapeutic treatment of diseases of human and animal tissue,” are considered intended use limitations. These limitations are not considered to hold any patentable weight since they do not function to result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP 2111.02 [R-2].

Dees et al. describe a variety of halogenated xanthene compounds that are generally highly soluble in aqueous solution (see col. 5, lines 1-6). Representative halogenated xanthene compounds of Dees et al. include the disodium salt of 4,5,6,7-Tetrabromoerythrosin; see col. 7, Table I. The agents of Dees et al. may be delivered to a target using by controlled agent delivery at, near or into the target, for example by encapsulation, the agent by also be delivered locally by means of injection (see col. 4, lines 35-52).

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The halogenated xanthene compounds of Dees et al. may also be delivered in conjunction with a delivery vehicle such as a surfactant, including topical creams, lotions, and liquids for intravenous or parenteral injection (col. 5, lines 44-54).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-2, 9-11, 19-20, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

Applicants have currently amended the instant claims to recite dipotassium salts of the halogenated xanthene in aqueous solution, wherein said halogenated xanthene is a compound selected from the group consisting of 4,5,6,7-Tetrabromoerythrosin, Monobromoerythrosin, Dibromoerythrosin, Tribromoerythrosin, Monochloroerythrosin, Dichloroerythrosin, Trichloroerythrosin, Monofluoroerythrosin, Difluoroerythrosin, Trifluoro-erythrosin, 2', 7'-Dichloro-4, 5,6,7-Tetrafluorofluorescein, 2', 4,5,6,7,7'-Hexafluoro-fluorescein and 4,5,6,7-Tetrafluorofluorescein. Applicants refer to Table 1 to support this amendment to the claims. However, there is no support in the specification as filed for dipotassium salts of the halogenated xanthene compounds recited in the instant claims. Moreover, although there is one example of a monopotassium modified halogenated xanthene described in Table 1, there is no support

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throughout the specification as filed for generic sodium, disodium, potassium or dipotassium salts of halogenated xanthenes in general. There is support for the specific disodium salts and potassium salt represented in Table 1, however the specification as filed does not generically teach disodium or dipotassium salts of halogenated xanthenes in general. These terms do not appear in the text of the specification as originally filed.

Moreover, Applicants have amended claim 20 to recite the range “greater than about 0.5% to less than about 20%.” However, Applicants do not provide any reference to the specification as filed for support of this amendment. The specification as filed at paragraph [0034] recites the limitation 0.5% in regards to the concentration of Rose Bengal in a saline solution, however this concentration does not support the range of greater than about 0.5% or less than about 20%.

Applicant's amendments to the claims are considered new matter, since the specification as filed does not provide either implicit or explicit support for the newly added amendments to the claimed.

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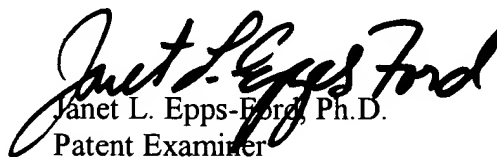
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Janet L. Epps-Ford, Ph.D.
Patent Examiner
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JLE